Complete Summary

GUIDELINE TITLE

Outcomes following traumatic spinal cord injury.

BIBLIOGRAPHIC SOURCE(S)

Paralyzed Veterans of America. Outcomes following traumatic spinal cord injury: A clinical practice guideline for health care professionals. Washington (DC): Paralyzed Veterans of America; 1999 Jul. 38 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Traumatic spinal cord injury

GUIDELINE CATEGORY

Diagnosis
Evaluation
Rehabilitation

CLINICAL SPECIALTY

Emergency Medicine
Neurological Surgery
Neurology
Nursing
Physical Medicine and Rehabilitation

INTENDED USERS

Health Care Providers
Health Plans
Managed Care Organizations
Nurses
Occupational Therapists
Patients
Physical Therapists
Physicians

GUIDELINE OBJECTIVE(S)

- To provide the best available answer to the question of what functional and psychosocial outcomes can be expected after spinal cord injury
- To make recommendations regarding the management of outcomes through appropriate assessment, goal setting, and documentation

TARGET POPULATION

Adolescent and adult individuals with traumatic spinal cord injury classified by The International Standards for Neurological and Functional Classification of Spinal Cord Injury (American Spinal Injury Association, 1996) into eight levels of injury (C1-3, C4, C5, C6, C7-8, T1-9, T10-L1, L2-S5)

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment

1. Initial neurological examination
2. Comprehensive neurological examination according to the International Standards for Neurological and Functional Classification
3. Periodic monitoring until recovery and throughout the individual's lifetime
4. Monitoring of functional ability throughout the rehabilitation process with treatment modification to maximize functional outcomes; periodic evaluation of functional status after achievement of functional goals
5. Assessment of quality of life (based on patient perception and the Diener's Satisfaction with Life Scale)

Goal Setting

1. Establishment of short- and long-term goals for functional independence
2. Goal-setting and treatment planning to improve quality of life

Documentation

1. Documentation of deviations in functional outcomes and social participation (e.g., use of the Craig Handicap Assessment and Reporting Technique)
2. Documentation of deviation in social participation and integration

MAJOR OUTCOMES CONSIDERED

- Motor recovery

- Functional independence
- Social integration
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A preliminary literature search of the MEDLINE database from 1966 to the present was conducted to estimate the volume of literature available and to identify the main issues associated with the topic. Key topic areas identified through discussion by the methodology team were:

- Functional outcomes and rehabilitation expectations for individuals with spinal cord injury
- Interventions, complications, and equipment that affect (either positively or negatively) expected functional outcomes
- Types of personnel and equipment necessary to achieve functional goals
- Studies of outcome instruments (e.g., the Functional Independence Measure and the Craig Handicap Assessment and Reporting Technique)
- Time-related considerations in determining the prognosis of expected functional gains
- Patient satisfaction, quality of care, quality of life, self-care, and self-concept
- Comorbidities that limit achievement of functional outcomes or quality of life

Articles of particular interest were those that analyzed and discussed functional outcomes by injury level. Topics ruled out of consideration were articles evaluating drugs, programs, or devices.

Only articles dealing with adults and adolescents (age $\geq$13 years) were included. Animal studies, though generally excluded, were used in several instances where they constituted the only evidence to support conclusions regarding biological mechanisms. The search was limited to articles published in English. Study designs employing clinical trials (randomized and nonrandomized), cohort studies, case control, case series, and cross-over studies were included. Case reports, instructional articles, and "n-of-one" studies were excluded. Articles describing qualitative research were excluded.

Review articles and overview articles examining functional outcomes for individuals with spinal cord injury were identified and retrieved if functional outcomes were topics of discussion. It is important to note that although review articles were included, they were not intended for use as evidence for the guideline. Rather, they were used to identify "gray literature" and to cross-reference with the literature search to ensure that all relevant articles on the topic had been identified and retrieved for analysis.

Key topic areas and words identified by the panel were translated, when necessary, into Index Medicus subheadings to search the MEDLINE (1996–1999) and the CINAHL (1982–1999) databases. Whenever possible, "exploded" Index Medicus subheadings were used, allowing the inclusion of more relevant literature than would be discovered using text word searches. Second-level searches were conducted using the major and minor Index Medicus subheadings retrieved from relevant articles.

More than 480 articles were identified through this search and their abstracts were reviewed, using the inclusion/exclusion criteria, for relevance to the management of functional outcomes. Of these articles, 145 articles met the inclusion/exclusion criteria and were retrieved. An additional 45 articles were retrieved for further analysis because they either did not have an abstract or their relevance was unclear.

NUMBER OF SOURCE DOCUMENTS

More than 480 source documents

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Hierarchy of the Levels of Scientific Evidence:

I. Large randomized trials with clear-cut results (and low risk of error)
II. Small randomized trials with uncertain results (and moderate to high risk of error
III. Nonrandomized trials with concurrent or contemporaneous controls
IV. Nonrandomized trials with historical controls
V. Case series with no controls

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Standardized data forms were used to extract relevant information from the articles found in the literature searches and the extracted information was then compiled into evidence tables. The methodology team, panel chair, and Paralyzed Veterans of America staff then categorized the articles according to the guideline topic areas. The evidence tables and articles were then sent to the panel members charged with writing the specific guideline sections. During the subsequent period, the methodology team responded to queries from the panel chair and members,

reviewed additional articles identified by panel members, and created and disseminated supplemental evidence tables as necessary.

For all evidence presented in this guideline, the methodology team employed the hierarchy first discussed by Sackett and later enhanced by Cook et al. and the United States Preventive Health Services Task Force. Additionally, each study was evaluated for internal and external validity.

Statistical meta-analyses or other specialized studies were conducted, as needed.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guideline development process adopted by the Spinal Cord Medicine Consortium consists of 12 steps, leading to panel consensus and organizational endorsement. After the steering committee chooses a topic, a panel of experts is selected who have demonstrated independent scientific investigation, publication, and leadership in the topic area. Following a detailed explication and specification of the topic by select steering committee and panel members, the methodology team review the international literature, prepare evidence tables, grade and rank the quality of research, and conduct statistical meta-analyses and other specialized studies, as needed. The panel chairperson then assigns specific sections of the topic to the panel members, based upon their area of expertise, and writing begins on each component using the references and other materials furnished by the methodology team.

The panel members complete their sections, a draft document is generated during the first full meeting of the panel. The panel incorporates new literature citations or other evidence-based information not previously available.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Categories of the Strength of Evidence Associated with the Recommendation:

A. The recommendation is supported by scientific evidence from properly designed and implemented controlled trials providing statistical results that consistently support the guidelines statement
B. The recommendation is supported by scientific evidence from properly designed and implemented clinical series that support the guidelines statement
C. The recommendation is supported by expert opinion

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Following a legal review to consider antitrust, restraint-of-trade, and health policy matters, the draft document was reviewed by predetermined clinical experts from each of the consortium organizations plus other select clinical experts and consumers. Fifty expert reviewers are acknowledged in the guideline. The review comments were assembled in a database and analyzed, and the document was revised to reflect the reviewer's comments. Following a second legal review, the document was distributed to all consortium organization governing boards. If substantive changes were required, the draft was given a final legal review.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The following provides a summary of the recommendations presented in the guideline document. The reader is directed to the original guideline for a detailed discussion of each of the following topics.

The levels of evidence (I-V), grades of recommendations (A-C), and strength of panel opinion (low, moderate and strong) are repeated at the end of the Major Recommendations.

Expected outcomes and their measurement are divided into four domains: motor recovery, functional independence, social integration, and quality of life. Within each domain, recommendations are offered regarding appropriate assessment, goal setting, and documentation. An overarching principle for all outcome assessment and documentation is that the measurement instruments should be standardized, well-validated, and reliable.

Expected Motor Recovery Outcomes

1. Perform a neurological examination to establish the diagnosis as soon as possible after a suspected spinal cord injury, ideally within 6 hours.

   Scientific evidence: III, V; Grade of recommendation: C; Strength of panel opinion: Strong

2. Perform a comprehensive neurological examination according to International Standards for Neurological and Functional Classification between 3 and 7 days after injury.

   Scientific evidence: V; Grade of recommendation: C; Strength of panel opinion: Strong

3. Monitor neurological status periodically until recovery has reached a plateau (overall recovery, zone-of-injury recovery, and ambulation potential).

   Scientific evidence: monitoring frequency: None; overall recovery: V; zone-of-injury recovery: V; ambulation potential: V; Grade of recommendation: monitoring frequency: Expert consensus; overall recovery: C; zone-of-injury recovery: C; ambulation potential: C; Strength of panel opinion: Strong

4. After neurological plateau has been reached, conduct periodic evaluations of neurological status throughout the individual's lifetime.

   Scientific evidence: V; Grade of recommendation: C; Strength of panel opinion: Strong

Expected Functional Independence Outcomes

5. Establish short- and long-term functional goals with the participation of the person served based upon a comprehensive, individualized assessment by a team of health-care professionals experienced in the care and treatment of people with spinal cord injury (See Table 6 in the guideline document for expected functional outcomes of individuals with motor complete spinal cord injury).

   Scientific evidence: V; Grade of recommendation: C; Strength of panel opinion: Strong

6. Monitor functional ability throughout the rehabilitation process, modifying treatment strategies to maximize functional outcome.

   Scientific evidence: None; Grade of recommendation: Expert consensus; Strength of panel opinion: Strong

7. After achievement of functional goals, conduct periodic evaluations of functional status throughout the individual's lifetime.

   Scientific evidence: III, V; Grade of recommendation: C; Strength of panel opinion: Strong

8. Document deviations in the achievement of functional outcomes (with reference to the normative data in Table 6 of the original guideline document) by groups of individuals receiving rehabilitation. Address such deviations in terms of improvement of clinical processes of care or unique population characteristics requiring risk adjustment.

   Scientific evidence: Unpublished data from the National Spinal Cord Injury Statistical Center system; Grade of recommendation: Expert consensus; Strength of panel opinion: Strong

Expected Social Integration Outcomes

9. After the initial acute care and rehabilitation phase, discharge individuals with spinal cord injury back into the community.

   Scientific evidence: III, V; Grade of recommendation: C; Strength of panel opinion: Strong

10. Focus on providing opportunities for societal participation in meaningful roles.

    Scientific evidence: Meta-analyses and unpublished data from the National Spinal Cord Injury Statistical Center; Grade of recommendation: Expert consensus; Strength of panel opinion: Strong

11. Document deviation in social participation and integration (with reference to Figures 5–8 of the original guideline document, which display normative data for the Craig Handicap Assessment and Reporting Technique) by groups who have completed rehabilitation. Address such deviations in terms of improvement of clinical processes of care or unique population characteristics requiring risk adjustment.

    Scientific evidence: Meta-analyses and unpublished data from the National Spinal Cord Injury Statistical Center; Grade of recommendation: Expert consensus; Strength of panel opinion: Strong

Expected Quality-of-Life Outcomes

12. Assess quality of life for individuals with spinal cord injury using direct perceptions of the individual involved.

    Scientific evidence: III, V and meta-analyses; Grade of recommendation: C; Strength of panel opinion: Strong

13. Facilitate opportunities for optimal quality of life within the full continuum of health-care and rehabilitation programs.

    Scientific evidence: III, V and meta-analyses; Grade of recommendation: C; Strength of panel opinion: Strong

Definitions:

Hierarchy of the Levels of Scientific Evidence:

I. Large randomized trials with clear-cut results (and low risk of error)
II. Small randomized trials with uncertain results (and moderate to high risk of error)
III. Nonrandomized trials with concurrent or contemporaneous controls
IV. Nonrandomized trials with historical controls
V. Case series with no controls

Categories of the Strength of Evidence Associated With the Recommendations

A. The guideline recommendation is supported by one or more level I studies
B. The guideline recommendation is supported by one or more level II studies
C. The guideline recommendation is supported only by level III, IV, or V studies

Levels of Panel Agreement with the Recommendation

Based on a 5-point scale (1 corresponding to neutrality; 5 representing maximum agreement)

Low
Mean agreement score of 1.00 to less than 2.33
Moderate
Mean agreement score of 2.33 to less than 3.67
Strong
Mean agreement score of 3.67 to 5.00

Note: If the literature supporting a guideline recommendation came from two or more levels, the number and the level of evidence supporting the studies are reported (e.g., a guideline recommendation that is supported by two studies, one a level III and the other a level V, the scientific evidence would be indicated as III, V). Likewise, if a guideline recommendation is supported by literature that crossed two categories, both categories are reported (e.g., a recommendation that includes both level II and III studies would be classified as category B, C).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations were based primarily on a comprehensive review of published reports. In situations where no published literature exists, recommendations were based on consensus of the panel members and outside expert reviewers.

The type of supporting evidence is identified for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The benefits of clinical practice guidelines for the spinal cord medicine practice community are numerous. Among the more significant applications and results are the following:

- Clinical practice options and care standards
- Medical and health professional education and training

- Building blocks for pathways and algorithms
- Evaluation studies of clinical practice guidelines use and outcomes
- Research gap identification
- Cost and policy studies for improved quantification
- Primary source for consumer information and public education
- Knowledge base for improved professional consensus building

Additional benefits include:

- Improved outcomes for patients with traumatic spinal cord injury.
- Motor-recovery: Information on expected neurological recovery can help in setting long-term goals during the acute period.
- Quality of Life: Improvements in subjective well-being may result in reduced secondary complications, activity limitations, and social role barriers due to increased engagement in self-care and health maintenance activities. Likewise, if barriers to performance of social roles are decreased, impairments related to secondary complications might be prevented or diminished.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline has been prepared based on scientific and professional information known about outcomes following traumatic spinal cord injury and its treatment in 1999. Users of this guideline should periodically review this material to ensure that the advice herein is consistent with current reasonable clinical practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Paralyzed Veterans of America. Outcomes following traumatic spinal cord injury: A clinical practice guideline for health care professionals. Washington (DC): Paralyzed Veterans of America; 1999 Jul. 38 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Jul

GUIDELINE DEVELOPER(S)

Consortium for Spinal Cord Medicine - Private Nonprofit Organization
Paralyzed Veterans of America - Private Nonprofit Organization

SOURCE(S) OF FUNDING

Paralyzed Veterans of America (PVA)

GUIDELINE COMMITTEE

Guideline Development Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Gale Whiteneck, PhD, Chairperson; Carole Adler, BA, OTR; Andrea K. Biddle, PhD, MPH; Sharon Blackburn, PT; Michael J. DeVivo, DrPH; Stephen M. Haley, PhD, PT; Robert D. Hendricks, PhD; Allen W. Heinemann, PhD; Kelly Johnson, RN, MSN, CFNP, CRRN; Ralph J. Marino, MD; Harley Thomas, BA; Robert L. Waters, MD; Gary M. Yarkony, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

American Academy of Physical Medicine and Rehabilitation - Medical Specialty Society
American Association of Spinal Cord Injury Nurses - Professional Association
American Association of Spinal Cord Injury Psychologists and Social Workers - Professional Association
American Paraplegia Society - Disease Specific Society
American Spinal Injury Association - Disease Specific Society

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: May be downloaded from the Paralyzed Veterans of America (PVA) Web site for a nominal fee.

Print copies: Available from the Paralyzed Veterans of America, 801 Eighteenth Street, NW, Washington, DC 20006.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 12, 2001. The information was verified by the guideline developer on March 27, 2001.

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